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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 8031-013-US U.S. APPLICATION NO. If known, see 37 CFR 1.5) 107580512 |
| INTERNATIONAL APPLICATION NO. PCT/US2004/039680 | INTERNATIONAL FILING DATE November 23, 2004 | PRIORITY DATE CLAIMED November 23, 2003 |
| TITLE OF INVENTION Treatment of a Condition in a Mammal with Administration of... | | |
| APPLICANT(S) FOR DO/EO/US Ichikawa, et al. | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). </p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ul style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). </p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ul style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> | | |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/580512 | INTERNATIONAL APPLICATION NO. PCT/US2004/039680 | ATTORNEY'S DOCKET NUMBER 8031-013-US |
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20. Other items or information:

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|--|--------------|---|--------------|----------------|--------------|
| The following fees have been submitted | | | | CALCULATIONS | PTO USE ONLY |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300 | | | | \$ 300 | |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200 | | | | \$ 200 | |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400 All other situations..... \$500 | | | | \$ 100 | |
| TOTAL OF 21, 22 and 23 = | | | | 600 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| 60 - 100 = | 0 /50 = | — | x \$250 | \$ 0 | |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | \$ 130 | |
| CLAIMS | | NUMBER FILED | NUMBER EXTRA | RATE | \$ |
| Total claims | | 92 - 20 = | 72 | x \$ 50 | \$ 3600 |
| Independent claims | | 2 - 3 = | 0 | x \$200 | \$ 0 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | | + \$360 | \$ 0 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ 4330 | |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½. | | | | | |
| Processing fee of \$130.00 for furnishing the English translation later to claimed priority date (37 CFR 1.492(j)). | | | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The ass by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per proper | | | | | |
| No authorization to change the additional fees. | | | | | |

10/580512
IAP9 Rec'd PCT/PTO 23 MAY 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. Please charge my Deposit Account No. 502235 in the amount of \$ 150.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.
- d. Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:



SIGNATURE

Michael B. Farber, Esq.
NAME

32,612

REGISTRATION NUMBER

10/580512
IAP9 Rec'd PCT/PTO 23 MAY 2006
PAPER

8031-013-US

IAP12 Rec'd PCT/PTO 23 MAY 2006

Certificate of Express Mailing

Under 37 CFR 1.10, I certify that the attached correspondence is being deposited with the United States Postal Service as Express Mail No. EV 669528748 envelope addressed to: Mail Stop: PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Date: May 23, 2006


Christina Dueñas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|------------------------------------|---|---------------------------|
| In re Application of: |) | Examiner: To Be Assigned |
| |) | |
| Yoshitaka Ichikawa, et al. |) | Group Art Unit: |
| |) | |
| Serial No.: U.S. National Stage of |) | |
| PCT/US2004/039680 |) | Docket No.: 8031-013-US |
| |) | |
| Filed: Herewith |) | Date Mailed: May 23, 2006 |
| |) | |
| For: Treatment of a Condition in a |) | |
| Mammal with Administration of |) | |
| Compounds and Methods of Use |) | |

TRANSMITTAL LETTER

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This submission is to effect entry of PCT Application PCT/US2004/039680 the United States National Stage under 35 U.S.C. § 371 and 37 C.F.R. § 1.495.

Accordingly, the following documents are transmitted:

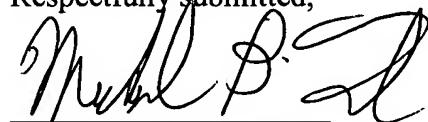
1. Transmittal Letter for Submission under 35 USC 371 with Fee Sheet indicating a fee payment of \$150.00, reflecting the basic national stage fee of \$150.00 for a small entity under 37 C.F.R. § 1.492(a) (3 pages);
2. An Application Data Sheet Under 37 C.F.R. § 1.76 giving biographical information on the inventors of the above-identified application as well as details of the claim for priority based on a previously-filed provisional application (2 pages); and
3. A copy of the above-identified PCT application. Because the above-identified PCT application was filed in the United States Patent and Trademark Office, the copy is not required under 37 C.F.R. § 1.495(b)(i). The copy is provided for convenience (60 pages).

Priority under 35 U.S.C. §§ 119 and 365 is hereby claimed for the national stage application. This priority is claimed to: (1) PCT Application No. PCT/US2004/039680, filed on November 23, 2004, and designating the United States; and (2) United States Provisional Patent Application Serial No. 60/524,698 filed on November 24, 2003, from which PCT Application No. PCT/US2004/039680 claimed priority.

Date: May 23, 2006

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9710 Scranton Road, Suite 170
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(858) 450-0099
(858) 450-9834 (Fax)

Respectfully submitted,



Michael B. Farber, Ph.D., Esq.
Reg. No.: 32,612